PTO/SB/08B (04-03)

Approved for use through 04/30/2003. OMB 0851-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

DESPA	te for form 1449/PTO				Complete if Known	
3005010	10 10 10 11 144 27 10			Applicati n Number	10/693,301	
INF	ORMATION	DIS	CLOSURE	Filing Dat	October 24, 2003	
STA	INFORMATION DISCLOSURE STATEMENT BY APPLICANT	First Nam d Inventor	Gary K. SCHWARTZ			
(Use as many sheets as necessary)				Art Unit		
	Ose as many sne	1612 82 1	lecessary)	Examiner Name		
Sheet	1	of	3	Attorney Docket Number	702-A-US	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
Re~	1	L. Zhang, L. Yank, X. Zheng, "A study of heliocobacterium pylori and prevention and treatment of chronic atrophic gastritis", J. Tradit. Chin. Med., 17:3-9, 1997.	
PC~	2	L.Q. Yang, M. Singh, E.H. Yap, G.C. Ng, H.X. Xu, and K.Y. Sim, "In vitro response of Blastocystis hominis against traditional Chinese medicine", J. Ethnopharmacol 55: 35-42, 1996.	
pc~	3	S.G. Franzblau and C. Cross, "Comparative in vitro antimicrobial activity of Chinese medicinal herbs. J. Ethnopharmacol", 15: 279-288, 1986.	
Pc~	4	L.C. Song, K.Z. Chen, J.Y. Zhu, "The effect of Coptis chinensis on lipid peroxidation and antioxidases activity in rats", Chung Kuo Chung Hsi I Chieh Ho Tsa Chih (1992 Jul) 12(7):421-3, 390.	
pc~	5	M. Umeda, S. Amagaya and Y. Ogihara, "Effects of certain herbal medicines on the biotransformation of arachidonic acid: a new pharmacological testing method using serum", J Ethnopharmacol (1988 May-Jun) 23(1):91-8.	
	6	G.D. Wang, Y.M. Zhang and X.Y. Xlong, "Clinical and experimental study of burns treated locally with Chinese herbs", Chung Hsi I Chieh Ho Tsa Chih (1991 Dec) 11(12):727-9, 709.	
PCM	7	W.M. Huang, J. Yan, and J. Xu, "Clinical and experimental study on inhibitory effect of sanhuang mixture on platelet aggregation", Chung Kuo Chung Hsi I Chieh Ho Tsa Chih (1995 Aug) 15(8):465-7	
	8	Y. Kobayashi, Y. Yamashita, N. Fuji, K. Takaboshi, T. Kawakami, M. Kamwamura, T. Mizukami, and H. Nakano, "Inhibitors of DNA topolsomerase I and II Isolated from the Coptis rhizomes", Planta Med 61: 414-418, 1995	
pc~	9	X.P. Fang, T.Z. Wang, H. Shang, H. Shual, D. Li, and C.K. Xie, "Quantitative determination of 5 alkaloids in plants of coptis from china". Chung Kuo Yao Tsa chih 14: 33-35, 1989	
p cm	10	C.W. Chi, Y.F. Chang, T.W. Cjao, S.H. Chiang, F.K. P'eng, W.Y. Lui, and T.Y. Liu, "Flowcytometric analysis of the effect of berberine on the expression of glucocorticoid receptors in human hepatoma HepG2 cells". Life Sci 54: 2099-2107, 1994	

Examiner Signature	Paul com	Date Considered	idial	05
A 10 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1			41 44 44 44	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 

2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.88. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

PTO/SB/08B (04-03)
Approved for use through 04/30/2003, OMB 0551-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
o a collection of information unless it contains a valid OMB control number.

	bstitute for form 1449/PTO  VEORMATION DISCLOSURI				Complete if Known	
3005010	1910/1011/11448/10			Application Number	10/693,301	
INFO	ORMATION	y Dis	CLOSURE	Filing Date	October 24, 2003	
STA	TEMENT	by a	PPLICANT	First Nam d Inv nt r	Gary K. SCHWARTZ	
				Art Unit		
	(Use as many sheets as necessary)			Examiner Name		
Sheet	2	of	3	Attorney Docket Number	702-A-US	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
pcm	11	M. Fukutake, S. Yokota, H. Kawamura, A. Iizuka, S. Amagaya, K. Fukuda, and Y. Komatsu, "Inhibitory effect of Coptidis Rhizoma and Scutellariae Radix on azoxymethane-induced aberrant crypt foci formation in rat colon", Bio. Pharm Bull 21: 814-817, 1998	
pc~	12	C.L. Qin, J.Y. Liu, and Z.M. Cheng, "Pharmacological studies on the effect of huanglian decoction on experimental gastric lesions in rats and antiemetic in pigeons", Chung Kuo Chung Yao Tsa Chih 19: 427-430, 1994	
Rem	13	C.Y. Yeung, F.T. Lee, and H.N. Wong, "Effect of a Popular Chinese Herb on Neonatal Bilirubin Protein Binding", Biol Neonate 58: 98-103, 1990	
Pan	14	E. Chan, "Displacement of bilirubin from albumin by berberine", Biol Neonate (1993) 63(4):201-8	
Pc ^	15	J.A. Marin-Neto, B.C. Maciel, A.L. Seecches, and L. Gallo, "Cardiovascular effects of berberine in patients with severe congestive heart failure", Clin Cardiol 11: 253-260, 1988	
pcm	16	X. Zeng and X. Zeng, "Relationship between the clinical effect of berberine on severe congestive heart failure and its concentration in plasma studied by HPLC". Biomed Chromatogr 13: 442-444, 1999	
pcm	17	X.S. Gao, "Absorptive capacity of upper gastrointestinal tract with Chinese herbal medicine", Chung Kuo Chung Hsi I Chieh Ho Tsa Chih (1993 Jul) 13(7):433-5, 390	
por	18	Y. Ozaki, H. Suzuki, and M. Satake, "Comparative studies on concentration of berberine in plasma after oral administration of coptidis rhizoma extract, its cultured cells extract and combined use of these extracts and glycyrrhizal radix extract in rats", Yakugaku Zasshi 113: 63-69, 1993	
pcm	19	P. Nurse, "Universal control mechanism regulating onset of M phase nature", (Lond) 344: 503-508, 1990	
PCM	20	W-C Chuang, D-S Young, L,K. Liu, and S-J Sheu, "Liquid chromatography-electrospray mass spectrometric analysis of coptidis Rhizoma", J. Chromatog 755L 19-26, 1996	

	Date Considered	(0/14/05
--	--------------------	----------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

PTO/SB/088 (04-03)

Approved for use through 04/30/2003. OMB 0851-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Office of University of U.S. Department of Commerce of U.S. Department of U.S. Depa

	Substitute for form 1449/PTO		<u> </u>		Compl te if Known	Ï
0,000,00				Applicati n Numb r	10/693,301	
INF	INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)	CLOSURE	Filing Dat	October 24, 2003		
STA		PPLICANT	First Nam d Inventor	Gary K. SCHWARTZ		
	///			Art Unit		
	(USB as many sho	eus as n	ecessary)	Examiner Name		_
Sheet	3	of	3	Attorney Docket Number	702-A-US	フ

Examiner	Cite	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of	
nitials*	No. <sup>1</sup>	the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
Pcm	21	C.M. Chen, H.C. Chang, "Determination of berberine in plasma, urine, and bile by HPLC", J. Chromatogr. 117-123, 1995	
pcm pcm	22	H. Zhang, T. Want, X. Fang, H. Shuai, and C. Xie, "Plants of coptis from tibet and yunnan", Chung Kuo Chung Yao Tsa Chih China Journal Of Chinese Materia Medica. 15: 326-328, 1990	
Pc~	23	D.L. Walker, J.M. Reid, and M.M. Ames, "Preclinical Pharmacology of bizelesin, a potent bifunctional analog of the DNA-binding antibiotic CC-1065", Cancer Chemother Pharmacol 34: 317-322, 1994	
	-		
PN-			

Examiner		Date / /	
Signature	_ falco	Considered 10 (14 (0)	

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

PTO/SB/08A (02-03)

Approved for use through 04/30/2003, OMB 0651-0031

U.S. Patent and Tredemark Office; U.S. DEPARTMENT OF COMMERCE

Under the Parapwork Reduction and of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1444-0

Sheet 1

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Cor	Complete if Known				
Application Number	10/693,301				
Filing Date	October 24, 2003				
First Named Inventor	Gary K. Schwartz				
Art Unit					
Examiner Name					
Attorney Docket Number	702-A-US				

U. S. PATENT DOCUMENTS						
Examiner tnitials*	Cite No. <sup>1</sup>	Document Number  Number-Kind Code <sup>2 (f known)</sup>	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
	<u> </u>	US-	1			
	<del> </del>	US-	<del> </del>			
	-	US-			<del> </del>	
	$\vdash$	US-	<del> </del>			
	$\vdash$	US-	-			
,	t	US-		······································		
		US-				
	1	US-				
	1	US-	1			
		US-				
		US-	1			
		US-				
		US-				
		US-				
		US-				
		US-		_		
		US-				
		US-				
		US-				

Examiner Initials*	Cite No.1	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	₽°
fen	1	Country Code <sup>3</sup> Number <sup>4</sup> 'Kind Code <sup>3</sup> (# known) PCT/CN01/01521	10-10-02	LI, HONGFEN		
			_			-
	<u> </u>	<u> </u>				

Examiner Signature	Va	ve.m	Date Considered	10/14/05

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patient Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patient documents, the indication of the year of the reign of the Emperor must precede the serial number of the patient document. Kind of document with the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will very depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

MAY 2 4 2004 By

PTO/SB/08B (04-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Petent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Substitute for form 1449/PTO PROPENSE.				re required to respond to a collection of information unless it contains a valid OMB control number.  Complete if Known		
3333333				Application Number	10/693,301	
INFORMATION DISCLOSURE				Filing Date	October 24, 2003	
STATEMENT BY APPLICANT			PPLICANT	First Named Inventor	Gary K. SCHWARTZ	
	// has an energy about	-4		Art Unit		
(Use as many sheets as necessary)				Examiner Name		
Sheet	2	of	2	Attorney Docket Number	702-A-US	
Suger	<u>  2</u>	of	] 2	Attorney Booket Number	/02-A-US	

Examiner	Cite	NON PATENT LITERATURE DOCUMENTS  Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of	
nitials*	No. <sup>1</sup>	the item (book, magazine, Journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
fcm	2	PCT International Search Report for Sloan-Kettering Institute for Cancer Research, Filed on October 25, 2003, Dated May 11, 2004.	
pm	3	Database PGPB on WEST, BASu et al. Treatment for Inflammatory bowel disease (IBD) and related conditions. PGPUB-DN 20020025348; February 26, 2003, Sections 0047-0048 and also claim 2.	
pon	4	Database PGPB on WEST, LU et al. Methods for inhibiting cancer growth, reducing infection and promoting general health with a fermented soy extract. PGPUB-DN 20020182274, December 5, 2002, entire document.	
<u></u>			
· · · · · · · · · · · · · · · · · · ·			

Examiner	V 0.1		Date	. 1	
Signature	Toul Cu	<b>∼</b>	Considered	101	14/05

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Onsidered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.